DEPARTMENT OF TRANSPORTATION

[4910-EX-P]

Federal Motor Carrier Safety Administration

[FMCSA Docket No. FMCSA-2015-0119]

Qualification of Drivers; Exemption Applications; Epilepsy and Seizure Disorders

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT

ACTION: Notice of final disposition.

SUMMARY: FMCSA announces its decision to exempt nine individuals from the regulatory requirement that interstate commercial motor vehicle (CMV) drivers have "no established medical history or clinical diagnosis of epilepsy or any other condition which is likely to cause loss of consciousness or any loss of ability to control a CMV." The exemptions enable these individuals to operate CMVs in interstate commerce.

DATES: The exemptions were effective on December 16, 2015. The exemptions expire on December 16, 2017.

FOR FURTHER INFORMATION CONTACT: Christine A. Hydock, Chief, Medical Programs Division, (202) 366-4001, fmcsamedical@dot.gov, FMCSA, Department of Transportation, 1200 New Jersey Avenue, SE, Room W64-113, Washington, DC 20590-0001. Office hours are from 8:30 a.m. to 5 p.m. e.t., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

I. Electronic Access

You may see all the comments online through the Federal Document Management System (FDMS) at: http://www.regulations.gov.

<u>Docket</u>: For access to the docket to read background documents or comments, go to http://www.regulations.gov and/or Room W12-140 on the ground level of the West Building, 1200 New Jersey Avenue, S.E., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Privacy Act: In accordance with 5 USC 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to www.regulations.gov, as described in the system of records notice (DOT/ALL-14 FDMS), which can be reviewed at www.dot.gov/privacy.

II. Background

On November 12, 2015, FMCSA published a notice announcing receipt of applications from 13 individuals requesting an exemption from the prohibition against persons with a clinical diagnosis of epilepsy or any other condition that is likely to cause a loss of consciousness or any loss of ability to operate a CMV in interstate commerce and requested comments from the public (80 FR 70065). The public comment period closed on December 14, 2015, and seven comments were received.

FMCSA has evaluated the eligibility of these applicants and determined that granting the exemptions to nine individuals would achieve a level of safety equivalent to or greater than the level that would be achieved by complying with the current regulation 49 CFR 391.41(b)(8).

The physical qualification standard for drivers regarding epilepsy found in 49 CFR 391.41(b)(8) states that a person is physically qualified to drive a CMV if that

person

Has no established medical history or clinical diagnosis of epilepsy or any other condition which is likely to cause the loss of consciousness or any loss of ability to control a CMV.

In addition to the regulations, FMCSA has published advisory criteria to assist medical examiners in determining whether drivers with certain medical conditions are qualified to operate a CMV in interstate commerce. The advisory criteria found in Appendix A to 49 CFR 391.41, states that:

If an individual has had a sudden episode of a non-epileptic seizure or loss of consciousness of unknown cause that did not require anti-seizure medication, the decision whether that person's condition is likely to cause the loss of consciousness or loss of ability to control a CMV should be made on an individual basis by the medical examiner in consultation with the treating physician. Before certification is considered, it is suggested that a 6-month waiting period elapse from the time of the episode. Following the waiting period, it is suggested that the individual have a complete neurological examination. If the results of the examination are negative and anti-seizure medication is not required, then the driver may be qualified.

In those individual cases where a driver had a seizure or an episode of loss of consciousness that resulted from a known medical condition (e.g., drug reaction, high temperature, acute infectious disease, dehydration, or acute metabolic disturbance), certification should be deferred until the driver has recovered fully from that condition, has no existing residual complications, and is not taking anti-seizure medication.

Drivers who have a history of epilepsy/seizures, off anti-seizure medication and seizure-free for 10 years, may be qualified to operate a CMV in interstate commerce. Interstate drivers with a history of a single unprovoked seizure may be qualified to drive a CMV in interstate commerce if seizure-free and off anti-seizure medication for a 5-year period or more.

As a result of medical examiners misinterpreting advisory criteria as regulation, numerous drivers have been prohibited from operating a CMV in interstate commerce

based on the fact that they have had one or more seizures and are taking anti-seizure medication, rather than an individual analysis of their circumstances by a qualified medical examiner based on the physical qualification standards and medical best practices.

In reaching the decision to grant these exemption requests, the Agency considered the 2007 recommendations of the Agency's Medical Expert Panel (MEP). The January 15, 2013 (78 FR 3069) Federal Register notice provides the current MEP recommendations which is the criteria the Agency uses to grant seizure exemptions.

These nine applicants have been seizure-free over a range of 5 to 44 years while taking anti-seizure medication and maintained a stable medication treatment regimen for the last two years. In each case, the applicant's treating physician verified his or her seizure history and supports the ability to drive commercially. A summary of each applicant's seizure history was discussed in the November 12, 2015 Federal Register notice and will not be repeated in this notice.

III. Discussion of Comments

Seven commenters responded to this notice, six of whom specifically expressed support for applicant Thomas Vivirito and one in support of her husband receiving an exemption. The Agency has determined that nine applicants should be granted an exemption.

IV. Basis for Exemption Determination

Under 49 U.S.C. 31136(e) and 31315(b), FMCSA may grant an exemption from the epilepsy/seizure standard in 49 CFR 391.41(b)(8) if the exemption is likely to achieve

an equivalent or greater level of safety than would be achieved without the exemption.

The exemption allows the applicants to operate CMVs in interstate commerce.

The Agency's decision regarding these exemption applications is based on an individualized assessment of each applicant's medical information, including the root cause of the respective seizure(s) and medical information about the applicant's seizure history, the length of time that has elapsed since the individual's last seizure, the stability of each individual's treatment regimen and the duration of time on or off of anti-seizure medication. In addition, the Agency reviewed the treating clinician's medical opinion related to the ability of the driver to safely operate a CMV with a history of seizure and each applicant's driving record found in the Commercial Driver's License Information System (CDLIS) for commercial driver's license (CDL) holders, and interstate and intrastate inspections recorded in the Motor Carrier Management Information System (MCMIS). For non-CDL holders, the Agency reviewed the driving records from the State Driver's Licensing Agency (SDLA). The Agency acknowledges the potential consequences of a driver experiencing a seizure while operating a CMV. However, the Agency believes the drivers granted this exemption have demonstrated that they are unlikely to have a seizure and their medical condition does not pose a risk to public safety.

Consequently, FMCSA finds that in each case exempting these applicants from the epilepsy/seizure standard in 49 CFR 391.41(b)(8) is likely to achieve a level of safety equal to that existing without the exemption.

V. Conditions and Requirements

The terms and conditions of the exemption will be provided to the applicants in the exemption document and includes the following: (1) each individual must remain seizure-free and maintain a stable treatment during the 2-year exemption period; (2) each individual must submit annual reports from their treating physicians attesting to the stability of treatment and that the driver has remained seizure-free; (3) each individual must undergo an annual medical examination by a certified Medical Examiner, as defined by 49 CFR 390.5; and (4) each individual must provide a copy of the annual medical certification to the employer for retention in the driver's qualification file, or keep a copy of his/her driver's qualification file if he/she is self-employed. The driver must also have a copy of the exemption when driving, for presentation to a duly authorized Federal, State, or local enforcement official.

VI. Conclusion

Based upon its evaluation of the nine exemption applications, FMCSA exempts the following drivers from the epilepsy/seizure standard in 49 CFR 391.41(b)(8), subject to the requirements cited above: Kenneth Lee Brown (WY), Douglas Ray Burkhardt (SD); Curtis Alan Hartman (MD); Wendell Frank Headley, Jr. (MO); Gregory L. Hrutkay (PA); Michael William Ketchum, Sr. (MI); Marion Franklin Legg, Jr. (MD); Alvin Clarence Strite (PA); and Thomas B. Vivirito (PA).

In accordance with 49 U.S.C. 31315(b)(1), each exemption is valid for 2 years, unless revoked earlier by FMCSA. The exemption will be revoked if the following occurs: (1) the individual fails to comply with the terms and conditions of the exemption;

(2) the exemption has resulted in a lower level of safety than was maintained prior to

being granted; or (3) continuation of the exemption would not be consistent with the

goals and objectives of 49 U.S.C. 31136 and 31315. If the exemption is still effective at

the end of the 2-year period, the individual may apply to FMCSA for a renewal under

procedures in effect at that time.

Issued on: April 29, 2016

Larry W. Minor

Associate Administrator for Policy

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